

Specification:

The applicant request that the with regards to the drawings and detailed description of the drawings in the specification please correct the Specification page 10 (line 17) as follows:

“Once the shaft **14** has been.....” to “Once the shaft **13** has been.....” (e.g. replace the number 14 with the number 14.

Claim Rejections:

The newly added and amended claims eliminate the objections made by the Examiner by the applicant specifically limiting claims so that the claims distinguish over the references cited. Specifically the claims eliminate the use or need of a plunger or penetrating shaft as required by the prior art of Guirguis. As cited in last Office Action dated 12/15/03 page 4 in which the Examiner clearly states that the Guriguis device **requires** the lid to be sealed activating the fluid releasing element. No such requirement is needed or desired by the present art in fact that and many other reasons are why this device is a marked advancement in the art. Without the cap being screwed on the device the **device will not work**. Try to understand, if a collector collects urine they want to close the device to prevent spillage but not necessarily read the assay or activate it. The cup could be given to a donor who urinates into the cup and then caps it. The assay will activate and the results will be shown to the donor, which could cause multiple problems, believe me, the analyst do not want the donors to observe the results of the test or be responsible for activation of the assay. With the present art the donor could urinate into the device, place a cap on it or not and hand it back to the collector/analyst. When the collector/analyst had time they will activate the device when they are ready for analysis. Again, this is a **marked** advancement in the art not capable by the prior art. No such limitation exist with the present art. Which is a method using a cup that has a shaft that is inherently dangerous to the user and non-dysfunctional unlike the present art. The device links the cap and the plunger in together requiring more than one step to just activate the device if possible. The device of Guirguis in no way resembles the device of the present art and even if one could apply the art of Guirguis a completely different cup design there would be no way to take the prior art of Guirguis and create the present and novel art of Smith and Lanier. This places the application in condition for allowance.

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the newly amended claims 1 and 5 all define patentably

over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

The Claims Rejection Under 35 USC § 102

Again, the newly amended claims have overcome the Examiners rejection of claims 1 and 5 under 35 U.S.C. 102(e) as being anticipated by Guirguis. This reference describes a method for the collecting and testing fluid using a plunger (spike) that is dangerous to the user (donor) and recipient (lab tech) much less the plastic would probably shatter upon first causing a bio-hazard as the specimen would no longer be contained by the prior art device of Guirguis. The antiquated technology of Guirguis is many years old and was never implemented because it does not work and has nothing to do with the present art of a method for the diagnostics determination of analytes of interest using a cup that requires no plunger, spikes, interaction with the lid, etc. The Guirguis has no similar reference even remotely resembling the present art. The attempt to use an ancient prior art that lacks implementation is a strained interpretation of the present art and has no relative bearing. The applicant would urge the examiner to use any of the examples as taught in the present specification and find the same example in any of Guirguis specification. The current device does not use a spike or have need for this limitation and this limitation is used in the claims of the present art. The present art does not use a lid as a prerequisite or a plunger (spike) and demonstrates distinct physical features that clears any § 102 rejections with reference to Guirguis. Guirguis device requires the use of a first chamber, a third chamber, a releasing element (plunger/spike), a lid with teeth with one-way rotation. It goes on and on. The Smith and Lanier patent has no such **limitations**. The physical features of Smith are completely different (**novel**) from that of Guirguis clearing the claims of Smith from any §102 rejections. This is patentably distinct and "novel" in structure and functionality over the Guirguis device. Because of this and other reasons the Smith and Lanier device is not limited to all of the requirements of the Guirguis device.

Again, rejection to newly amended claims 1 and 5 as being anticipated by Guirguis under 35 U.S.C. § 102 should be reversed because Guirguis does not teach applicant's limitations as claimed, i.e., without the use of a plunger, tilting, plenums, etc., as required by Guirguis. Therefore, Guirguis fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." The device of Smith and Lanier uses a **"new principle of operation"** in that include the use of a device with a activation means that does not spike / plunger though plastic to activate (endangering lives) to perform assays for analytes of interest. Never taught by Guirguis or any other prior art. The applicants invention solves a different problem than the reference, and such differences are cited in the new and amended claims, such as no requirement for a spike, tilting, etc.. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith and Lanier recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

Again, rejection to newly amended claims 1 and 5 as being anticipated by Guirguis under 35 U.S.C. § 102 should be reversed because Guirguis does not teach applicant's limitations as claimed and therefore, Guirguis fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single

reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."

As the Appellant and other courts have cited, hindsight view of prior art is not allowable. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in *re Fritch supra*, 1784.

Thus the applicant submits that the present invention clearly recites novel physical subject matter which distinguishes over any possible use of Guirguis.

The Novel Physical features of Claims 1 and 5 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 102.

It is impermissible to use hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a *prima facie* case of the obviousness, it is necessary for the examiner to present *evidence*, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the *motivating force* which would impel one skilled in the art to do what the *applicant has done*."

The Novel Physical Features Of New and Amended Claims 1 and 5 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 102.

Conclusion

The applicant disagrees with the Examiner on page 5 of the Office Action dated 12/15/03. The lid the applicants invention is not equivalent to Guirguis by any stretch of the imagination. The following table is self-explanatory. How can the devices be equivalent if ones if required to activate the device the does not require it?

<u>The Lid:</u>	<u>Smith/Lanier</u>	<u>Guirguis</u>
Lid Activates the Device	NO	YES
Lid Closes the Container	YES	YES
Lid is Required for Activation	NO	YES

The applicant makes not claims to requirement for the lid to activate, In fact, the applicant cites this in this response page 7 and the specification pages 5, 6, etc., of the application. From page 6 of the specification "It has been found that the foregoing objects of the present art are accomplished in accordance with this invention by providing a collection and analyzing cup that is designed to collect the specimen and immediately have the lid secured onto the top of the cup. **Then the user can analyze the specimen when ready.**" The last sentence has nothing to do with the activation of the cup.

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,



Jack V. Smith



Kerstin Lanier

____ Applicant Pro Se _____

P.O. BOX 156

Arden, NC 28704

Phone: 828-650-0410 or 828-275-0343 or 800-905-4272

Fax: 828-650-0359

Certificate of Mailing

I certify that on the date below I have mailed the above response to the Office Action dated 12/15/03 by First Class mail or better to the Commissioner for Patents at P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 05/12/04

Inventor's Signature: _____



Jack V. Smith